REMARKS/ARGUMENTS

Claims 48, 49, 51-53, 55-59 and 66-81 are pending. Claims 57, 66 and 76-81 have been amended. Claims 1-47, 50, 54, and 60-65 were previously cancelled without intending to abandon or to dedicate to the public any patentable subject matter. The Applicants contend that no new matter has been added by the amendments.

Withdrawn Rejection Under 35 U.S.C. § 112, Second Paragraph

The Examiner has withdrawn the previous rejection under 35 U.S.C. § 112, second paragraph.

Objections

The Examiner has objected to Claims 76-81 for typographical errors. Applicants have amended these Claims to remove the errors. Withdrawal of this objection is respectfully requested.

Rejections Under 35 U.S.C. § 112, First Paragraph

The Examiner has maintained the rejection of Claims 48, 49, 53, 55-58, 66, 67, 73 and 74 as well as rejecting Claims 76-81 under 35 U.S.C. § 112, first paragraph, as lacking enablement necessary for the skilled artisan to practice the invention commensurate in scope with the pending claims. The Examiner argues that while the claims are enabled for a method to select a cancer patient who is predicted to benefit from therapeutic administration of gefitinib comprising detecting the level of E-cadherin polynucleotides in a sample of tumor cells from said patient, comparing said level to a level of E-cadherin polynucleotides in a sample of tumor cells from a subject having the same type of cancer and that is resistant to gefitinib, and selecting the patient as being predicted to benefit from therapeutic administration of gefitinib if the level of E-cadherin polynucleotides in the sample of tumor cells from said patient is higher than the level of E-cadherin polynucleotides in the sample of tumor cells from the subject that is resistant to gefitinib, the claims are not enabled for methods to select a cancer patient, who is predicted to benefit from therapeutic administration of just any EGFR inhibitor, just any agonist thereof, or just any drug having substantially similar biological activity as just any EGFR inhibitor. Solely

to expedite prosecution, Applicants have amended the claims to focus on lung cancer patients and therapeutic administration of the specific EGFR inhibitors gefitinib and erlotinib and expression levels of a polynucleotide that correlates with sensitivity and resistance to the specific EGFR inhibitors. Support for gefitinib is found throughout the specification and support for erlotinib as an EGFR inhibitor is found on page 2, line 1 of the specification.

In addition, as described by the Examiner on page 9 of the Office Action, the specific EGFR inhibitors gefitinib and erlotinib both share the same mechanism of action (i.e. act as ATP mimetics) that would thus enable one of skill in the art to predictably substitute one for the other to perform the claimed method.

In making the rejection for the lack of enablement for methods of evaluating a patient with a cancer other than NSCLC or for the administration of an EGFR inhibitor other than gefitinib, it appears to be the Examiner's position that only those cancers and EGFR inhibitors tested and described in the Examples section of the specification are enabled. Applicants respectfully disagree. As stated in the guidance provided by section 2164.02 of the MPEP, compliance with the enablement requirement of 35 U.S.C.112, first paragraph, does not turn on whether an example is disclosed, and an applicant need not have actually reduced the invention to practice prior to filing. While the lack of a working example is a factor to be considered, Applicants need not describe all actual embodiments, and the presence of only one or no working example should never be the sole reason for rejecting claims as being broader than the enabling disclosure.

Applicants therefore submit that the pending claims are sufficiently supported and enabled in the specification to meet the requirements of 35 U.S.C. § 112, first paragraph and that no undue experimentation would be required by one of skill in the art to perform the method of the presently claimed invention. Withdrawal of this rejection is respectfully requested.

Double Patenting

The Examiner has maintained the provisional rejection of Claims 48, 49, 53, 55-58, 66, 67, 73, 74, and in addition, claims 76-81 under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-15 of U.S. Patent Application Serial No. 11/781,946. There are currently no claims from either the instant application or co-pending

Application No. 11/781,946. The Examiner has acknowledged that the Applicants will address this provisional rejection when allowable subject matter from these applications has been identified.

Based upon the foregoing, Applicants believe that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,
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